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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,546	03/20/2001	Karl Kolter	51284	9100
26474	7590	06/18/2004	EXAMINER	
KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036				SPEAR, JAMES M
		ART UNIT		PAPER NUMBER
		1615		

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/811,546	KOLTER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	James M Spear	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 December 2003.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-19 and 21-24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,3-19 and 21-24 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

The Request for Continued Examination and amendment filed December 04, 2003 has been entered.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-19 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kolter et al US 6,064,334. The claims remain rejected for the reasons set forth in Paper No. 6, mailed March 26, 2003. While applicants have amended claim 1 to recite the limitation “from greater than 20 to less than or equal to 80 percent a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone”, the reference discloses amounts of from 5 to 30 percent by weight of a binder. Column 4, lines 50-53. The scope of applicants’ claims read on the prior art of record. It is the position of this office that one skilled in the art would not be limited in showing the amount of the binder. The novelty of the Kolter et al reference appears to be in the combination of polyvinyl acetate and N-vinylpyrrolidone polymers. See column 2, lines 37-47. One skilled in the art would immediately envision using amounts greater than 20 to less than or equal to 80 percent of a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone to provide other types of oral dosage forms.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-19 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolter et al in view of Ortega US 4,837,032. Kolter et al shows applicants' solid oral dosage form as explained above. Kolter et al does not recite delayed release of active agents as in applicants' claims. However Kolter et al shows release of the active ingredients within a time of from 0.1 to 1 hour. Claim 1. Ortega is relied on for showing sustained release dosage forms wherein a polymeric matrix is utilized. Oretega uses polyvinylpyrrolidone and polyvinyl acetate primarily in greater amounts than Kolter et al. Ortega in describing the invention uses terminology such as controlled steady release and extended period of time to describe release rates of up to 12 hours. Claim 11. Column 2, lines 50-62. The prior art clearly shows it is well known to use combinations of polymers to modify the release of active agents from oral solid dosage forms. Kolter in showing that using polymers in lower amounts for there negligible effect on disintegration and release of active ingredient further suggest that increased amounts would modify the release rates. It would be reasonable to use greater amounts of the polymer matrix comprised of polyvinyl acetate and polyvinylpyrrolidone as taught by Ortega in the Kolter et al dosage form. The motivation being each inventors desire to tailor a dosage form to provide release of an active agent at a desired site to provide optimum efficacy.

Claims 1, 3-19 and 21-24 are rejected.

Claims 2 and 20 have been canceled.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*James M. Spear*  
James M Spear  
Primary Examiner  
Art Unit 1615

June 12, 2004